UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO., LTD., Plaintiffs, v. RICHARD HART and MARIE LOUISE TRUDEL-HART, Defendants.	Civil Action No. 12-CV-3479 (SAS)

PLAINTIFFS' MOTION *IN LIMINE* TO EXCLUDE PORTIONS OF THE EXPERT REPORT AND TESTIMONY OF THOMAS D. BECZE

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Plaintiffs Sekisui America Corporation and Sekisui Medical Co., Ltd. (together, "Plaintiffs" or "Sekisui") submit this motion *in limine* to exclude portions of the expert report and testimony of Thomas Becze, pursuant to Federal Rule of Evidence 702.

PRELIMINARY STATEMENT

Defendants proffer Mr. Becze solely to rebut the testimony of two of Plaintiffs' expert witnesses: Carrie Kuehn, an expert on compliance with U.S. Food and Drug Administration ("FDA") requirements, and Timothy Ulatowski, an expert on submissions to the FDA pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act. Mr. Becze's testimony rebutting Mr. Ulatowski's expert opinions lacks any reliable basis or analysis and should be excluded. Mr. Becze simply attacks Mr. Ulatowski's opinion regarding the 510(k) submission from American Diagnostica, Inc. ("ADI") as "pure conjecture," and provides no suitable foundation on which such an attack could be based. Indeed, Mr. Becze conceded that, in making such a statement, he did not even review the 510(k) submission at issue. Mr. Becze further seeks to make statements at trial about 510(k) submissions and FDA processes that he likewise has no basis to make. The Court recognized as much at the September 27, 2013 pre-motion conference:

> But Becze conceded at deposition that he cannot opine on the FemTel 510(k) submissions because he's not read them and that he agrees that there are circumstances when a submission is likely to fail. He's never worked at the FDA or overseen the 510(k) submission process and cites no reliable basis for his opinion so it seems to me that his opinion on the 510(k) process and FemTel's submissions are beyond his expertise, not to mention he didn't review the submissions. Maybe he's reacting to this report without understanding the subject area or the underlying document. So that's my take on Becze.

(Declaration of Craig Whitney ("Whitney Decl."), Ex. A (Sept. 27, 2013 Tr. at 24:13-22).)

In short, Mr. Becze's rebuttal of Mr. Ulatowski's expert testimony is unreliable and inadmissible under Rule 702.

BACKGROUND

Mr. Ulatowski opines in his expert report on the viability of ADI's 2009 510(k) submission for clearance to market a breast cancer diagnostic known as Femtelle in the United States. Specifically, Mr. Ulatowski opines that the 510(k) submission was destined to fail due to insufficient clinical data and other information, including the lack of design history files for Femtelle. He bases his opinion on his review of ADI's 2007 and 2009 510(k) submissions and related correspondence with the FDA. (*See* Whitney Decl., Ex. B (Ulatowski Report at 24-31).) Mr. Ulatowski also draws on his expertise of the 510(k) submission process from his 36-plus years of experience at the FDA. (*See id.* at 3). Indeed, during Mr. Ulatowski's tenure at the FDA, he was directly responsible for reviewing 510(k) submissions, and became "thoroughly familiar" with such submissions, having made decisions on hundreds of them. (*See id.* at 5-6, 33.) Mr. Ulatowski further opines that Sekisui's decision ultimately to withdraw the Femtelle 510(k) submission following the acquisition of ADI was the right decision in light of significant deficiencies in the required documentation and information. (*See id.* at 31-33.)

In rebuttal, Mr. Becze opines that Mr. Ulatowski's conclusion that the Femtelle 510(k) submission was destined to fail is "pure conjecture." (Whitney Decl., Ex. C (Becze Report at 6).) Mr. Becze further opines that Mr. Ulatowski's conclusion regarding Sekisui's decision to withdraw the 510(k) submission is "baseless." (*Id.*)[1] Aside from his unsubstantiated (and later contradicted) statement that it is "impossible to predict the outcome of a 510(k) submission" (*id.*), Mr. Becze offers no basis for his summary dismissal of Mr. Ulatowski's conclusions—no studies or other data, no explanation of how he reaches his own conclusion and no discussion of whether or how his own conclusion draws on his experience. Mr. Becze's lone attempt to

[1] Mr. Becze also opines that "[s]imilarly baseless is Mr Ulatowski's conclusion that if ADI had responded to the 'outstanding deficiencies' the resubmission could have triggered an FDA inspection," with no foundation to support that opinion. (*Id.*)

support his opinion is by reference to the FDA's ability to dismiss a 510(k) submission by issuing a "Refusal to File," a purely procedural tool used by the FDA to ensure that the submission is reviewable in the first place, and which has no bearing on the substance of the submission. (*See* Whitney Decl., Ex. D (Center for Devices and Radiological Health's Premarket Notification 510(k) Refuse to Accept Policy).)

At his deposition, Mr. Becze admitted that he has never worked at the FDA, or at any other government agency. (*See* Whitney Decl., Ex. E (Becze Dep. at 22:4-9).) Further, he admitted that he had *not even read* the Femtelle 510(k) submission on which Mr. Ulatowski opines. (*Id.* at 247:10-12.) This glaring flaw apparently did not trouble Mr. Becze, who claimed, "I don't feel like there's any more information that I would need to be able to refute the fact that something is destined to fail when it isn't destined to fail." (*Id.* at 250:25-251:5.) Finally, Mr. Becze admitted that, contrary to his earlier conclusions, there may be some circumstances in which it is apparent that a 510(k) submission *is* likely to fail. (*Id.* at 257:13-258:18 (admitting that, if the submitter of a 510(k) lied in the submission, or was unable to provide requested information, the submission would not be approved).) In the face of these numerous shortcomings, Mr. Becze nevertheless opined that it was "impossible" to reach the opinion Mr. Ulatowski reaches. (*Id.* at 244:18-24.)

ARGUMENT

Federal Rule of Evidence 702 governs the admissibility of expert testimony. Rule 702 provides that "scientific, technical, or other specialized knowledge" may be admissible where such testimony "will assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. Such testimony is only admissible, however, if: (1) "the testimony is based on sufficient facts or data;" (2) "the testimony is the product of reliable principles and methods;" and (3) "the expert has reliably applied the principles and methods to the facts of the

case." *Id.* The district court is charged with a "gatekeeping" duty to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999). Exclusion is the only remedy sufficient to protect against the inherent power of expert evidence, which can be "quite misleading because of the difficulty in evaluating it." *Daubert*, 509 U.S. at 595 (citation omitted).

Mr. Becze's proffered testimony to rebut Mr. Ulatowski's expert opinion must be excluded because it is neither based on sufficient facts or data nor the product of reliable principles and methods. Mr. Ulatowski opines that the Femtelle 510(k) submission was destined to fail, basing that conclusion on his review of the submission itself and related correspondence with the FDA, coupled with his extensive expertise in the area of 510(k) submissions. Mr. Becze, on the other hand, did not read the Femtelle 510(k) submission—the very document that is the subject of discussion—and claimed instead at deposition that it is simply impossible for Mr. Ulatowski to have reached the conclusion he reached. Mr. Becze then quickly contradicted himself when he admitted that, in certain circumstances, it may be apparent that a 510(k) submission will fail. Courts routinely preclude expert testimony when it is based solely on an expert's own authority without any supporting foundation. *See*, *e.g.*, *Grdinich v. Bradlees*, 187 F.R.D. 77, 82 (S.D.N.Y. 1999) ("Because 'knowledge connotes more than subjective belief or unsupported speculation,' there is no reliable foundation for [the] expert opinion.") (citing *Daubert*, 509 U.S. at 590); *Donnelly v. Ford Motor Co.*, 80 F. Supp. 2d 45, 49-50 (E.D.N.Y. 1999) (finding expert's report unreliable where "nothing in his report explains the reasoning or methodology" by which he reached his opinions and where the expert failed to explain the data, studies, or reasoning employed).

Mr. Becze also lacks any experience either with the FDA or overseeing the 510(k) submission process, and fails to explain how whatever experience he does have provided a basis for his opinion rejecting Mr. Ulatowski's conclusions. To be admissible, an expert's opinion based on his experience must show how that experience informs his opinion. *See*, *e.g.*, *Mahoney v. JJ Weiser & Co.*, No. 04 Civ. 2592, 2007 U.S. Dist. LEXIS 79460, at *14 (S.D.N.Y. Oct. 25, 2007) ("Where . . . an expert's opinion is based on the expert's experience, courts focus on the relationship between the experience and the opinion and whether the latter is rationally related to the former.") (citation omitted). Mr. Becze's failure to link his opinion to his experience is fatal to its admissibility.

Nor can Mr. Becze's reference to the FDA's "Refusal to File" process serve as a reliable basis for his opinion and, in fact, it highlights his lack of expertise in the area of 510(k) submissions. Mr. Becze appears to claim that receipt of a "Refusal to File" notice would be the only mechanism by which it is possible to determine that a 510(k) submission was destined to fail. (*See* Whitney Decl., Ex. C (Becze Report at 6); Ex. E (Becze Dep. at 245:3-18).) In 1993, the Center for Devices and Radiological Health ("CRDH"), which Mr. Ulatowski describes as "responsible for evaluation and clearance or approval of new medical devices" (*id.*, Ex. B (Ulatowski Report at 3)), issued a notification with regard to its 510(k) "Refuse to Accept" policy.[2] (*See id.*, Ex. D (Center for Devices and Radiological Health's Premarket Notification 510(k) Refuse to Accept Policy).) The CRDH provided a checklist to be used in this process, and noted:

> It is intended that this checklist will be used to separate out those 510(k)s which are sufficiently complete to permit in-depth scientific reviews from those that are lacking important regulatory elements or are so grossly deficient in a particular

[2] Mr. Becze acknowledged that there is no meaningful distinction between a "Refusal to File" and a "Refusal to Accept." (*Id.*, Ex. E (Becze Dep. at 242:9-24).)

> element such that, in effect, the element has not been provided. . . . The reviewer should keep in mind that *the purpose of this acceptance review is to ensure reviewability, not the substantial equivalence of the 510(k)*.

(*Id.* at 5 (emphasis added).) The CRDH's policy makes clear that, contrary to Mr. Becze's conclusion, a "Refusal to Accept" has little, if any, bearing on the merits of a 510(k) submission, and is instead relevant only to whether a submission contains all of the required elements that will enable it to be reviewed. In other words, the fact that ADI's 2009 510(k) submission for Femtelle did not receive a "Refusal to Accept" notice does not contradict Mr. Ulatowski's conclusion that it was destined to fail. Thus, Mr. Becze's reference to the "Refusal to File" process is largely irrelevant and does not provide a basis for his sweeping condemnation of Mr. Ulatowski's opinions.

Finally, contrary to Defendants' assertion in their opposition to Plaintiffs' pre-motion letter (Dkt. 58 at 2), Plaintiffs' objections to Mr. Becze's report and testimony are not matters for cross-examination. The portions of Mr. Becze's report and testimony at issue are entirely lacking in any basis sufficient for admissibility under Rule 702, and thus the cases cited by Defendants are inapposite. *See Cedar Petrochemicals, Inc. v. Dongbu Hannong Chem. Co.*, 769 F. Supp. 2d 269, 285 (S.D.N.Y. 2011) (admitting expert reports where conclusions were based on "reliable results from tests conducted by independent consultants" and court concluded that experts "have made limited assertions tied directly to the limited evidence they had available to them"); *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995) (rejecting challenge to expert report where report was based on "a range of factors," including the expert's experience, studies, and multiple data sources). Mr. Becze's report contains none of the supporting elements required for admissible expert testimony. Where an expert's proffered opinion is nothing more than an *ipse dixit* conclusion, it is inadmissible. *See Donnelly*, 80 F. Supp. 2d at 50.

CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court grant Plaintiffs' motion *in limine* excluding Mr. Becze's proffered testimony in rebuttal to Mr. Ulatowski's expert report.

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